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12M1/0726

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**NOTICE OF ALLOWANCE
AND ISSUE FEE DUE**

- ☐ Note attached communication from the Examiner
☐ This notice is issued in view of applicant's communication filed _____

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/163,581	12/07/93	007	HENLEY III, R	1205 07/26/94
First Named Applicant	BARBERICH, TIMOTHY J.			

TITLE OF INVENTION METHOD FOR TREATING ASTHMA USING OPTICALLY PURE (R)-ALBUTEROL

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1 SPC8905	514-649.000	C93	UTILITY	YES	\$585.00	10/26/94

THE FEE DUE IS THE AMOUNT IN EFFECT AT THIS TIME. IF THE AMOUNT OF THE ISSUE FEE INCREASES PRIOR TO PAYMENT, APPLICANT WILL BE NOTIFIED OF THE BALANCE OF ISSUE FEE DUE.

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT.

PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

- I. Review the SMALL ENTITY Status shown above.
If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
 - A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the patent and Trademark Office of the change in status, or
 - B. If the Status is the same, pay the FEE DUE shown above.
- II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, Part C of this notice should also be completed and returned.
- III. All communications regarding this application must give series code (or filing date) and serial number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to contrary.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, pay of 1/2 the FEE DUE shown above.

IMPORTANT REMINDER: Patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.



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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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08/163,581 12/07/93 BARBERICH

T. SPC8905
EXAMINER

HENLEY III, R

12M1/0726

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ART UNIT PAPER NUMBER

1205
DATE MAILED:

40/I
07/26/94
7-22-94

NOTICE OF ALLOWABILITY

PART I.

- ☒ This communication is responsive to The Amendment + declaration filed May 11, 1994
- ☒ All the claims being allowable. PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.
- ☒ The allowed claims are 1-6 and 8 (renumbered as 1-7 respectively)
- ☐ The drawings filed on _____ are acceptable.
- ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received. ☐ not been received. ☐ been filed in parent application Serial No. _____, filed on _____.
- ☒ Note the attached Examiner's Amendment.
- ☒ Note the attached Examiner Interview Summary Record, PTOL-413.
- ☒ Note the attached Examiner's Statement of Reasons for Allowance.
- ☐ Note the attached NOTICE OF REFERENCES CITED, PTO-892.
- ☐ Note the attached INFORMATION DISCLOSURE CITATION, PTO-1449.

PART II.

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

- ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
- ☐ APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.
 - ☐ Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No. _____. CORRECTION IS REQUIRED.
 - ☐ The proposed drawing correction filed on _____ has been approved by the examiner. CORRECTION IS REQUIRED.
 - ☐ Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED.
 - ☐ Formal drawings are now REQUIRED.

Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

Attachments:

- ☒ Examiner's Amendment
- ☒ Examiner Interview Summary Record, PTOL-413
- ☒ Reasons for Allowance
- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Citation, PTO-1449

- ☐ Notice of Informal Application, PTO-152
- ☐ Notice re Patent Drawings, PTO-948
- ☐ Listing of Bonded Draftsmen
- ☐ Other

[Signature]

RAYMOND L. HENLEY III
PATENT EXAMINER
GROUP 120 - ART UNIT 125

EXAMINER'S AMENDMENT/REASONS FOR ALLOWANCE

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Philip E. Hansen on July 13, 1994.

The application has been amended as follows:

IN THE CLAIMS:

In claims 1 and 6, line 4, ---chronically--- has been inserted before the word "administering".

In claim 6, line 3, ---chronic administration of racemic--- has been inserted before the word "albuterol"..

IN THE ABSTRACT:

At the last line, ---chronic administration of racemic--- has been inserted before the term "albuterol".

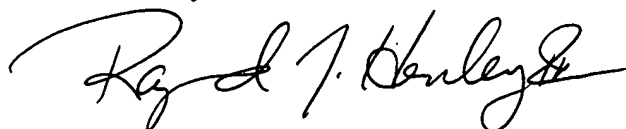
The following is an Examiner's Statement of Reasons for Allowance:

Applicants' amendment and the declaration of T. Scott Johnson filed May 11, 1994 have been received, entered and favorably considered. The Examiner agrees

with the statements made by both applicants and the declarant that support exists in the present specification for avoidance of the side effects associated with chronic therapy for asthma. Moreover, it is the Examiner's opinion that it would not have been expected from the prior art of record that the R(-) isomer of albuterol would possess the improved side effect profile as established in the declaration of Dr. Aberg filed July 23, 1993, i.e., that the R(-) isomer of albuterol does not cause the hypersensitivity reaction normally associated with long-term racemic albuterol administration in patients suffering from asthma. This fact is highly significant and compels the Examiner to conclude that the presently claimed invention would not have been obvious under 35 U.S.C. § 103. The Examiner is guided in his opinion by the finding of the Board of Patent Appeals and Interferences in the unpublished decision of Ex parte Ferrari et al. (Appeal No. 629-61) dated January 28, 1987 in which a similar factual situation existed. Further comments relating to this decision as well as the significance of the hypersensitivity reaction associated with racemic albuterol administration, which are hereby adopted by the Examiner, are presented in the paper entitled "Record of Telephonic Interview" filed by applicants on August 5, 1993.

Thus, for the reasons above, claims 1-6 and 8 are deemed to be allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably **accompany** the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."



RAYMOND J. HENLEY III
PATENT EXAMINER
GROUP 120 - ART UNIT 125